

*facie* case of obviousness. *In re Baird*, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994) ("The fact that a claimed compound may be encompassed by a disclosed generic formula does not by itself render that compound obvious."); *In re Jones*, 958 F.2d 347, 350, 21 USPQ2d 1941, 1943 (Fed. Cir. 1992) (Federal Circuit has "decline[d] to extract from *Merck & Co. v. Biocraft Laboratories Inc.*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir. 1989)] the rule that...regardless of how broad, a disclosure of a chemical genus renders obvious any species that happens to fall within it."). See also *In re Deul*, 51 F.3d 1552, 1559, 34 USPQ2d 1210, 1215 (Fed. Cir. 1995)." M.P.E.P. §2144.08 (II).

Therefore, the fact that  $\alpha$ AED is encompassed by the genus in Schwartz is not sufficient by itself to establish a *prima facie* case of obviousness. Since that is the only argument put forth by the Examiner, the burden of establishing a *prima facie* case of obviousness has not been met, and this rejection cannot stand.

Furthermore, the three criteria that must be met to establish any case of *prima facie* obviousness still apply: (1) there must be some suggestion or motivation to modify or combine references, (2) there must be a reasonable expectation of success, and (3) the references must teach or suggest all the claim limitations. The teaching or suggestion to make the combination and the reasonable expectation of success must both be found in the cited art, not the applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991).

The first criterion is not met for the claimed invention. The Examiner has not identified a suggestion or motivation for one of ordinary skill in the art "to select the claimed species or subgenus from the disclosed prior art genus. See, e.g., *Ochai*, 71 F.3d at 1569-70, 37 USPQ2d at 1131; *Deuel*, 51 F.3d at 1557, 34 USPQ2d at 1214 ("[A] *prima facie* case of unpatentability requires that the teachings of the prior art suggest *the claimed compounds* to a person of ordinary skill in the art." See, M.P.E.P. §2144.08 (II) (A) (4).

The considerations to be taken into account include: (a) the size of the genus, (b) the express teachings, (c) the teachings of structural similarity, (d) the teachings of similar properties or uses, (e) the predictability of the technology, and (f) any other teaching to support the selection of the species or subgenus.

Here, the prior art genus is: (a) extremely large ( $10^{64}$  members), (b) there are no express teachings to select the claimed compounds, (c) the preferred compounds in the cited art are arguably 16 fluoro compounds, not the compounds of the invention which are not substituted at 16, (d) the expected mechanisms of action between the claimed compounds and the preferred compounds of the cited art are different, and (e) steroid hormone activity can be structure specific, such that the activity of structurally related species can be difficult to predict. See, for example, *Ortho Pharmaceutical Corp. v. Smith*, 22 U.S.P.Q. 1119, 1125 (1992) and *Brenner v. Manson*, 148 U.S.P.Q. 689, 694 (1966).

Thus, the cited art provides no motivation to select the claimed compounds, and the requirement for making a *prima facie* case of obviousness has not been met. Therefore, Applicant respectfully requests that the rejection of claims 15-18 under 35 U.S.C. § 103 for allegedly being obvious, be withdrawn, and that the claims be allowed.

*Claim Rejections - 35 U.S.C. § 112, second paragraph*

Claims 15 to 18 stand rejected under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite. The Examiner states that the "formula in claims 15-18 should recite "RO-" and not "OR". Applicant respectfully traverses this rejection as it applies to the claims as amended.

Independent claim 15 has been amended to clarify the formula as requested by the Examiner. Claims 16 to 18 depend from claim 15. Therefore the rejection is moot.

Based on the above, Applicant respectfully requests that the rejection under 35 U.S.C. § 112, second paragraph, be withdrawn and that the claims be allowed.

SUMMARY

In view of the above, Applicant asserts that the claimed invention is in condition for allowance and notification to that effect is respectfully requested. In order to facilitate rapid allowance, the Examiner is invited to contact the undersigned at the telephone number below.

Any fees due in relation to the filing of this Response are hereby authorized to be deducted from Deposit Account No. 501536.

Respectfully submitted,

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